

## IO Reimbursement: Be Proactive and Prepared

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As with other high-cost treatments, integration of immunotherapies into practice requires a thorough understanding of payer policies and requirements for reimbursement. Working within the clinical policies of third party payers is paramount to a successful foundation for payment. Almost all payer types have created clinical policies for immuno-oncology (IO) agents. Payers (commercial, federal- and state-funded plans) create clinical policies to provide guidance on medical necessity for an IO agent(s) from the payer's point of view. Commercial payers often have written policies, while government payers may set generic parameters with diagnosis codes that must be followed. These generic parameters require the practice to interpret if guidelines are met prior to therapy.

### *How are you staying current on payer clinical policies and proactively managing relationships with your payers?*

A key step in successful reimbursement is for providers to become thoroughly familiar with each payer's clinical policy and understand any required biomarker testing or exclusions. For example, clinical policies for IO agents may require biomarker testing for some agents but not others, even when such testing is not indicated by the FDA label. Payers' clinical policies may also include: exclusion criteria based on past therapies (or lack of those therapies), length of coverage for therapies, or past or current concurrent disease states (e.g., Hepatitis C). When payers lack a clinical policy, the program or practice intending to deliver the IO agent must request a complementary pre-determination.

As more new agents and new indications receive FDA approval, another reimbursement challenge occurs. Payers' clinical policies

and published drug compendia may lag 3-6 months behind published FDA approvals. Providers need to be proactive. Submit a pre-determination that includes recent peer-reviewed literature and an updated product package insert.

Anticipate that you will need to obtain prior authorization for immunotherapies and, with the exception of Medicare, that you will need to ask payers for permission to treat with these agents. Even though you receive prior authorization, your denials team needs to be adept at writing appeals proving medical necessity with these agents. Be ready for denials on authorization requests for agents that are used outside of approved two IO agent combinations, or an IO agent and other chemotherapy agent (IV or oral) for patients previously treated with a checkpoint agent, or when sequential therapy is interrupted.

Establishing a foundation for proactively managing payer relationships and leveraging those relationships with IO is beneficial. Payers usually have a process for submission of clinical policy material; however, convincing payers to consider a change in policy is challenging unless sufficient peer-reviewed literature is available. The largest opportunity lies with your local Medicare fiscal intermediary's development of Local Coverage Determinations (LCDs). The fiscal intermediary will take into consideration the NCCN Compendia and NCCN Practice Guidelines and view these as the gold standard for medical necessity, as well as for successful reconsiderations of an LCD policy.



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